



**UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM42/0623

EXAMINER

PART NUMBER PAPER NUMBER

1616

7

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED: 06/23/98

5/5/97
8/26/97
2/6/98
2/17/98

☒ This application has been examined

☒ Responsive to communication filed on

☐ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.

- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 62-136 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims _____ have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 62-136 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____ Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

Art Unit 1616

Claims 62-136 have been presented for examination and will be reviewed on their merits. The preliminary amendments, filed May 5, 1997 and August 26, 1997, wherein claims 1-61 were canceled and claims 62-136 were added, was entered prior to this examination on the merits.

The Information Disclosure Statements received on May 5, 1997, February 6, 1998, and on February 17, 1998 have been entered and were fully considered in this Office Action.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 62-136 are rejected under 35 U.S.C. § 103 as being unpatentable over Lambert et al. (5,552,133), Unger (5,705,187), Yan et al. (5,556,610), and Schneider et al. (5,413,774).

These claims appear to be directed towards a microbubble composition which comprises two gases. Independent claim 62 requires that one of the gases be selected from a specific group of medium chain (C₅-C₈) perfluorocarbons. Independent claim 109 has the limitation that one of the gases has a boiling point above 37°C. Independent claim 123 requires that the microbubbles be surrounded by a proteinaceous membrane.

Lambert et al. (col. 4, lines 59-60) teach protein encapsulated microbubbles and specifically teach that the gas may be composed of a mixture of compounds. Unger ('187) teaches that microbubbles comprising multiple gases may be prepared. Unger further teaches several gases which have boiling point above 37°C including several of the gases set forth in claim 62. Yan et al. teach albumin

Art Unit 1616

encapsulated microbubbles comprising at least two gases. Schneider et al. (col. 5, lines 34-47) teach microbubbles comprising two gases (by partial substitution of one gas for another and further exemplify (e.g. example 1) that such microbubbles may be encapsulated in a proteinaceous shell.

While none of the prior art references teach specific examples which would fall within the three claim designated Markush groups, it would have been obvious to those of ordinary skill in the art that such composition could be prepared because Lambert et al., Unger, Yan et al., and Schneider et al. each teach that compositions comprising multiple gases with claim designated limitations may be prepared. One of ordinary skill would have been motivated to select a proteinaceous shell or a high boiling point gas because they are clearly presented as viable options by the prior art.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

In view of the objections /rejections to the pending claims set forth above, no claims may be allowed at this time.

The processing of this application can be expedited by providing the following information or changes in your next amendment:

- Proper cross-reference to related applications for which priority is claimed under 35 U.S.C. § 120 in the first paragraph of the specification - including current status (M.P.E.P. 201.11)
- Early filing of an Information Disclosure Statement that includes a PTO-1449 form wherein the document number, publication date, inventor, country of publication, and US patent classification is listed for each patent document and wherein the author, title, journal, volume, issue (if known), pages, and year of publication is listed for all journal references (M.P.E.P. 609). A timely prior art disclosure by the Applicant aids in a speedy prosecution and helps to insure that the patent granted is both valid and enforceable.
- A descriptive title (M.P.E.P. 606 and 606.01). Please note that 1-2 word titles are generally unacceptable.
- Ensuring that each of the drawings presented (if any) are described in the brief description of the drawings. Please note that if a drawing has more than one figure in it (e.g. Figures 1A and 1B), each of the figures must be individually described.
- An abstract which is descriptive of the disclosed invention and contains the chemical structure of the active ingredient(s).
- Correction of any ambiguities in the specification which may lead to a printer inquiry, such as blank spaces which appear to be omissions.
- Correction of any typographical errors in the application.

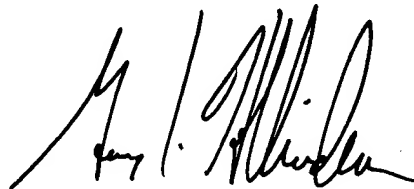
Art Unit 1616

Examiner Hollinden has moved to Art Unit 1616. Please include the new Art Unit number on all future correspondence as it will greatly expedite handling of papers.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at 703/308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15 1989.

Any inquiry concerning this Office Action or any earlier Office Actions in this application should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521. Dr. Hollinden's office hours are from 6:30 am to 3:00 pm, Monday through Friday.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.

A handwritten signature in black ink, appearing to read 'Gary E. Hollinden', is positioned above the printed name.

Gary E. Hollinden, Ph.D.
Primary Examiner
Group 1616